IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): K. Bortlik et al. Appl. No.: 10/057,660

Conf. No.: 4348

Filed: January 25, 2002

Title: PRIMARY COMPOSITION COMPRISING A LIPOPHILIC BIOACTIVE

COMPOUND

Art Unit: 1651

Examiner: R.A. David Docket No.: 112701-593

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

RESPONSE TO NON-COMPLIANT APPEAL BRIEF

Sir:

This Response is submitted in reply to the Notice of Non-Compliant Appeal Brief dated May 9, 2007.

REMARKS

In response to the Notice of Non-Compliant Appeal Brief dated May 9, 2007, Appellants have included a statement in the "Status of Claims" section of the Appeal Brief to address the informality cited by the Patent Office. The compliant version of the Appeal Brief is attached as Exhibit A without copies of the cited references, which were previously submitted.

Appellants submit that the present Appeal Brief is compliant under 37 CFR 41.37. Appellants respectfully request reconsideration of the Appeal Brief and submit that the Patent Office has failed to establish anticipation under 35 U.S.C. § 102 with respect to the rejection of the claimed invention. Accordingly, Appellants respectfully submit that the anticipation rejection is erroneous in law and in fact and should therefore be reversed.

The Director is authorized to charge any fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-593 on the account statement.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

BY

Robert M. Barrett Reg. No. 30,142

Customer No. 29156

Dated: May 16, 2007

EXHIBIT A

THE UNITED STATES PATENT AND TRADEMARK OFFICE BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant(s): K. Bortlik et al. Appl. No.: 10/057,660

Conf. No.: 10/05/,6

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Title: PRIMARY COMPOSITION COMPRISING A LIPOPHILIC BIOACTIVE

COMPOUND

Art Unit: 1651

Examiner: R.A. David Docket No.: 112701-593

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

APPELLANTS' APPEAL BRIEF

Sir:

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on February 2, 2007. This Appeal is taken from the Final Rejection in the Office Action dated August 3, 2006 and the Advisory Action dated December 11, 2006.

I. REAL PARTY IN INTEREST

The real party in interest for the above-identified patent application on Appeal is Nestec S.A. by virtue of an Assignment dated April 17, 2002 and recorded at reel 012823, frame 0530 in the United States Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

Appellants' legal representative and the Assignee of the above-identified patent application do not know of any prior or pending appeals, interferences or judicial proceedings which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision with respect to the above-identified Appeal.

III. STATUS OF CLAIMS

Claims 65-76, 78-82 and 86-93 are pending in the above-identified patent application. Claims 1-64, 77 and 83-85 were previously canceled. Claims 65-76, 78-82 and 86-93 stand rejected. Therefore, Claims 65-76, 78-82 and 86-93 are being appealed in this Brief. A copy of the appealed claims is included in the Claims Appendix.

IV. STATUS OF AMENDMENTS

A Final Office Action was mailed on August 3, 2006. Appellants filed a Response on November 22, 2006 in reply to the Final Office Action. An Advisory Action was mailed on December 11, 2006. In the Advisory Action, the Examiner entered the amendments but maintained the anticipation rejections. A copy of the Final Office Action and the Advisory Action are attached as Exhibit A and Exhibit B, respectively, in the Evidence Appendix.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of the invention by way of reference to specification and/or figures for each of the independent claims is provided as follows:

Independent Claim 65 is directed to a primary composition for oral use comprising a mixture of (i) at least one lipophilic bioactive compound (page 2, lines 2-3; page 5, lines 11-14) and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound (page 2, lines 2-3; page 5, lines 21-26).

Independent Claim 90 is directed to a primary composition for oral use comprising a mixture of (i) at least one lipophilic bioactive compound (page 2, lines 2-3; page 5, lines 11-14) and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound (page 2, lines 2-3; page 5, lines 21-26), wherein the lipophilic bioactive compound is present in an amount of about 0.05 to 50% by weight of the composition (page 6, lines 10-12) and the whey protein is present in an amount of about 5 to 90% by weight of the composition (page 6, lines 13-14) and wherein the whey protein and the lipophilic bioactive compound are present in a weight ratio of about 1:1 to 500:1 (page 6, lines 14-18).

Although specification citations are given in accordance with C.F.R. 1.192(c), these reference numerals and citations are merely examples of where support may be found in the specification for the terms used in this section of the Brief. There is no intention to suggest in any way that the terms of the claims are limited to the examples in the specification. As demonstrated by the reference numerals and citations, the claims are fully supported by the specification as required by law. However, it is improper under the law to read limitations from the specification into the claims. Pointing out specification support for the claim terminology as is done here to comply with rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the reference numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

 Claims 65-76, 78-82 and 86-93 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,643,623 to Schmitz et al. ("Schmitz"). A copy of Schmitz is attached herewith as Exhibit C.

VII. ARGUMENT

A. <u>LEGAL STANDARDS</u>

Anticipation under 35 U.S.C. §102

Anticipation is a factual determination that "requires the presence in a single prior art disclosure of each and every element of a claimed invention." Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987). Moreover, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil of California, 814 F.2d 628, 631 (Fed. Cir. 1987) (emphasis added).

Federal Circuit decisions have repeatedly emphasized the notion that anticipation cannot be found where less than <u>all</u> elements of a claimed invention are set forth in a reference. See, e.g., *Transclean Corp. v. Bridgewood Services, Inc.*, 290 F.3d 1364, 1370 (Fed. Cir. 2002). In this regard, a reference disclosing "substantially the same thing" is not enough to anticipate. *Jamesbury Corp. v. Litton Indust. Prod., Inc.*, 756 F.2d 1556, 1560 (Fed. Cir. 1985). A reference must clearly disclose each and every limitation of the claimed invention before anticipation may be found.

To establish inherent anticipation, the Federal Circuit has stated that "extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999) (emphasis added).

In relying on inherency, the Patent Office requires an examiner to supply an applicant with a "basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis added). If the examiner is successful in showing a sound basis, for example, that the products of the applicant and the prior art are the same, the burden then shifts to the applicant to show that they are not. See. MPEP 2112.

B. THE CLAIMED INVENTION

Independent Claim 65 recites, in part, a primary composition for oral use. The composition comprises a mixture of at least one lipophilic bioactive compound and a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound.

Independent Claim 90 recites, in part, a primary composition for oral use. The composition comprises a mixture of at least one lipophilic bioactive compound and a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound. The lipophilic bioactive compound is present in an amount of about 0.05 to 50% by weight of the composition. The whey protein is present in an amount of about 5 to 90% by weight of the composition. The whey protein and the lipophilic bioactive compound are present in a weight ratio of about 1:1 to 500:1.

C. THE REJECTION OF CLAIMS 65-76, 78-82 AND 86-93 UNDER 35 U.S.C. §102(b) SHOULD BE REVERSED BECAUSE SCHMITZ DOES NOT ANTICIPATE THE CLAIMED INVENTION

Regarding Claims 65-76, 78-82 and 86-93, the Examiner alleges that *Schmitz* discloses every element of the present claims. Appellants respectfully submit that the anticipation rejection in view of *Schmitz* is improper and traverse the rejection for at least the reasons set forth below.

The Affidavit shows that Schmitz fails to disclose a mixture of at least one
lipophilic bioactive compound and a whey protein in an amount effective to
increase the bioavailability of the lipophilic bioactive compound

Independent Claims 65 and 90 recite, in part, a primary composition for oral use comprising a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound ("LBC"). As such, the composition of the present claims is directed to a homogenous mixture of LBC within whey protein in an amount effective to increase bioavailability of the LBC. For

example, rather than being in a discrete form, such as an encased core as in Schmitz, the LBC of the present claims is distributed uniformly through the protein component thereby providing the unexpected and important benefits of increased bioavailability of the LBC. In fact, the present claims are focused on distribution of the lipophilic compound in a matrix of whey protein and not as a core in an encapsulated product. This is due to the fact that the emulsifiers naturally present in tomato oleoresin, for example, or other added emulsifiers, replace the proteins in the interface, which precludes an encapsulation process. The Examiner has failed provide any support in Schmitz for this novel element.

In contrast, Schmitz fails to disclose or suggest a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound as required, in part, by independent Claims 65 and 90. In fact, Schmitz fails to provide any guidance or support regarding same.

Instead, Schmitz is directed to a health food product containing a first component in the form of a discrete portion (i.e. core) from a second component provides enhanced in vivo oxidative defense indices and prevents or attenuates exercise-induced in vivo oxidative stress as indicated by cellular and/or tissue modification. The first component includes an antioxidant mixture containing a blend of antioxidants selected from all-trans beta-carotene, a mixture of cis beta-carotenes, all-trans alpha-carotene, a mixture of cis alpha-carotenes, all-trans lycopene, a mixture of cis lycopenes, all-trans gamma-carotene, a mixture of cis gamma-carotenes, zeta-carotene, phytofluene, phytoene, vitamin C, vitamin E and curcumin. Internalization and integration of the above nutrients within a lipid containing core of the food product facilitates absorption of the fat-soluble components in the gastrointestinal tract following consumption, increases shelf-life and minimizes degradation of these labile compounds by minimizing exposure to heat, light and/or oxygen, and prevents disadvantageous yellow/orange coloration of the outer material of the food product.

The Examiner alleges that Schmitz teaches food product compositions comprising 20-40% whey, 0.1-1% carotenoids and 1.5-3.5% vitamin E and C in Example 6. Example 6 of Schmitz discloses a first component containing 10-20% of whey protein that is used as carrier in the lipid-containing core and 0.1-1% cartenoid blend. The second component contains only carrier compounds and no LBC, as specified in the description stating "[t]he second component comprises a carbohydrate and/or fat and/or protein, and other nutritive and non-nutritive

compounds." See, Schmitz, column 2, line 66 to column 3, line 1. Consequently, the Schmitz composition is in an encapsulated form and therefore heterogeneous. Appellants respectfully submit that one skilled in the art would find that Schmitz entirely urges use of a lipid-containing core and does not teach that the lipid core may be replaced by whey protein as a matrix.

Moreover, to demonstrate the failure of the referenced art to teach the claimed elements, Appellants submitted an Affidavit under 37 C.F.R. §1.132 ("Affidavit" attached hereto as Exhibit D) on February 2, 2007. The Affidavit demonstrates the deficiencies of the prior art. As supported by the Affidavit, Schmitz fails to disclose or suggest a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound as required, in part, by the present claims. Instead, Schmitz is directed to a health food product containing a first component in the form of a discrete portion within a second component. The first component includes antioxidants in a lipid containing core of the food product. As a result, because Schmitz teaches including antioxidants in a lipid-based core, the antioxidants in Schmitz's composition are in an internalized and heterogeneous form, which is distinguishable from the homogenous mixture of the LBC and whey protein in accordance with the present claims.

In the Advisory Action, the Examiner alleges that the present claims do not require that the composition be homogenous and, thus, the argument that Schmitz does not teach a homogenous mixture of LBC and whey is not commensurate in scope with the claims. See, Advisory Action, page 2. However, Appellants respectfully submit that one having ordinary skill in the art would understand that the claimed "mixture" of the present claims requires a homogenous dissolution as opposed to a product containing two discrete portions as in Schmitz.

For example, the term "mixture" is defined as "the state of being mixed." See, Merriam-Webster OnLine, definition of "mixture." Merriam-Webster OnLine further defines "mix" as "combining or blending into one mass." See, Merriam-Webster OnLine, definition of "mix." In the specification, several examples illustrate that the whey protein may be dissolved in a solvent. Similarly, the LBC may also be dissolved in another solvent. Upon dissolution of the whey protein and the LBC, the solutions are then mixed before the solvents are evaporated. See, specification, page 8, line 19-page 10, line 11. Therefore, as evidenced by the specification, one having ordinary skill in the art would understand that "mixing" the two solutions means combining the solutions or blending the solutions into one homogenous solution.

Similarly, Merriam-Webster OnLine further defines "homogenous" as being of uniform structure or composition throughout. See, Merriam-Webster OnLine, definition of "homogenous." Since the specification clearly illustrates several examples where the LBC is dissolved into one solvent, the whey protein is dissolved into another solvent, and the two solutions are mixed (i.e. combined or blended into one mass) before evaporating the solvent, one having ordinary skill in the art would understand that the resulting mixture is a homogenous blend of the LBC and whey protein. Thus, in view of the specification, one having ordinary skill in the art would understand that the LBC of the present claims is mixed into and throughout the whey protein matrix in a homogenous manner (i.e. there is no discrete separation of the LBC and the whey protein).

In contrast to the present claims, Schmitz discloses a health food product containing a first component in the form of a discrete portion (i.e. core) from a second component. Appellants respectfully submit that one having ordinary skill in the art would not use the term "mixture" when describing the relationship of a first the inner core and a second outer component of a product. Instead, they would be considered adjacent or discrete. A "mixture," on the other hand, refers to a greater level of integration of two components rather than placing them next to each other.

As illustrated by the Figures in Schmitz (Figures 1-5), the first component is clearly not mixed with the second component in the same way as required by the present claims. For example, the product is illustrated as having a discrete, core-like component and a distinct second component. One of ordinary skill in the art would recognize that one could not achieve the illustrated product structure by mixing the two separate portions. Such mixing could not provide a distinct first component, but rather would produce a more intimate/homogenous mixture of the first and second portions. Thus, it would be clear to one of ordinary skill in the art that the "mixture" of the present claims refers to producing a more intimate/homogenous mixture of LBC and whey protein than that provided by the food product in Schmitz.

Further, in part, the propriety of this anticipation rejection lies in the interpretation of the claim language "comprising a mixture of" (emphasis added). To properly interpret claim language, the Federal Circuit has held that claims must be read in view of the specification, of which they are a part. Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995). Moreover, intrinsic evidence in the form of the patent specification should guide claim

construction. Along these lines, the Federal Circuit recently reinforced the importance of the specification when interpreting claim language:

The claims, of course, do not stand alone. Rather, they are part of "a fully integrated written instrument," Markman, 52 F.3d at 978, consisting principally of a specification that concludes with the claims. For that reason, claims "must be read in view of the specification, of which they are a part." Id. at 979. As we stated in Vitronics, the specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." 90 F.3d at 1582.

Phillips v. AWH Corp., 415 F.3d 1303, 1315 (Fed. Cir. 2005) (emphasis added). Therefore, the specification remains the "single best guide" to interpreting the term "mixture" as used by Appellants in the specification. Moreover, as demonstrated above, the specification should be read as providing a homogenous mixture of LBC and whey protein. Thus, one having ordinary skill in the art would understand that the LBC is homogenously mixed into and throughout the whey protein matrix in view of the specification (i.e. there is no distinct separation of the LBC and whey protein). It is axiomatic that the Appellants' definition of a term controls how that term is interpreted.

The Affidavit shows that Schmitz fails to disclose enhancing the bioavailability of a lipophilic bioactive compound using whey protein

In addition to teaching the inclusion of an antioxidant mixture in a food product only in an encapsulated/discrete form, Schmitz fails to disclose or suggest enhancing bioavailability of the carotenoid blend. Rather Schmitz only contemplates using whey protein as a carrier. For example, Schmitz specifies that the antioxidants are preferably localized in a lipid-based carrier within the food product to promote absorption and digestion of the carotenoid blend and curcumin. See, Schmitz, column 3, lines 19-22. Schmitz only cites whey protein as an example of different kinds of proteins that can be used as a carrier while its important function related to bioavailability is not recognized or appreciated. Appellants respectfully submit that one skilled in the art would find that Schmitz entirely urges antioxidants that are localized in a lipid-based carrier within the food product and does not suggest enhancing the bioavailability of the cartenoid blend.

As supported by the Affidavit, Schmitz's product fails to achieve increasing the bioavailability of the LBC with whey protein in accordance with the present invention. Schmitz specifies that the antioxidants are preferably localized in a lipid-based carrier within the food product. See, Schmitz, column 3, lines 19-22. In contrast to Schmitz, the composition of the present claims is directed to a homogenous mixture of LBC within whey protein in an amount effective to increase bioavailability of the LBC. For example, rather than being in a lipid-based carrier as in Schmitz, the LBC of the present claims is distributed uniformly through a whey protein thereby providing the unexpected and important benefits of increased bioavailability of the LBC. Appellants respectfully submit that one skilled in the art would find that Schmitz entirely urges use of a lipid-containing core and does not teach that the lipid core may be replaced by a whey protein matrix.

The Examiner alleges that the present claims are not patentable over Schmitz because Schmitz inherently posses the ability to increase the bioavailability of the LBC with whey protein. See, Office Action, page 5. Specifically, the Examiner asserts that "the claiming of a new use, function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable." Id. However, Appellants respectfully submit that Schmitz does not inherently posses the advantages of the present claims.

The fact that a certain result or characteristic <u>may</u> occur or be present in the prior art is <u>not</u> sufficient to establish the inherency of that result or characteristic. See, MPEP 2112. In re Rijckaert, 9 F.3d 1531, 1534 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); In re Oelrich, 666 F.2d 578, 581-82 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999) (emphasis added). Moreover, at the patent prosecution stage, the Patent Office requires an examiner to supply an applicant with a "basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex parte Levy, 17 USPO2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis added). Not only has this

standard not been met, Appellants have submitted an Affidavit that illustrates the opposite, as is demonstrated above.

As detailed above, inherency requires that the cited references necessarily (i.e. always or automatically) possess the claimed elements. See, e.g., Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1381-82 (Fed. Cir. 2003). In other words, the food products disclosed by Schmitz would have be required to always result in an increased bioavailability of the LBC with whey protein to meet the present claims. However, Appellants have demonstrated that this is not the case because the embodiments disclosed by Schmitz do not possess all of the elements of the present claims. See, Affidavit. Specifically, Appellants have demonstrated that examples having LBC mixed throughout the whey protein matrix show an increased bioavailability of the LBC. In contrast, the embodiments of Schmitz do not provide homogenously mixed first and second components, as was discussed previously and, thus, do not always posses the advantages of the present claims.

Appellants submit that they are not required to test every potential embodiment to show that they do not disclose the claimed properties. Moreover, the Examiner has not demonstrated that there is any reason that any of the other embodiments would meet the requirements of the present claims. Accordingly, Appellants submit that the inherency argument is improper and that Schmitz does not anticipate the present claims.

In sum, the cited reference fails to provide or recognize a solution to the present technical problem of enhancing the bioavailability of the LBCs as Appellants' invention has done. Schmitz only teaches ways to protect compounds from oxidation via internalization or containing within a lipid core and not increase the bioavailability of the LBC by dispersion of the LBC in a matrix of whey proteins as required, in part, by the present claims. While Schmitz may have sought to provide bioactive compounds for health-related purposes, it does not recognize or even achieve the bioavailability-enhancing function of whey protein that can be utilized by mixing the whey protein with an LBC.

For at least the reasons discussed above, Schmitz does not teach, suggest, or even disclose all of the elements of the present claims, and thus, fails to render the claimed subject matter obvious. The rejections under 35 U.S.C. §102(b) should be reversed because the Affidavit
properly overcomes the anticipation rejections of the pending claims

Appellants respectfully submit that the Affidavit properly overcomes the anticipation rejection of the pending claims with respect to the cited reference. In this regard, the Affidavit sufficiently and properly evidences that Schmitz fails to explicitly or inherently disclose or suggest compositions within the scope of the present invention. The Affidavit shows that the cited reference fails to disclose or suggest a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the LBC. Further, the Affidavit properly evidences that the cited reference fails to achieve increasing the bioavailability of the LBC with whey protein.

Moreover, Appellants provide examples regarding the novel composition comprising a mixture of at least one LBC and a whey protein in an amount effective to increase the bioavailability of the LBC. The improved composition provides, for example, the advantage that, when the LBC is mixed with a whey protein to form a mixture, the present invention makes available to a subject a LBC-containing composition with better bioavailability compared to consuming a LBC alone. The specification discloses particular examples regarding administration of the claimed composition and has shown that the composition's LBC availability is comparable to that of tomato puree or paste, which are products known to have the best bioavailability of lycopene. See, specification, page 10, line 18 to page 11, line 10.

For at least the reasons discussed above, *Schmitz* fails to teach, suggest, or even disclose independent Claims 65 and 90, and Claims 66-76, 78-82 and 86-93 that depend from either Claim 65 or Claim 90, and thus, fails to anticipate the present claims. Accordingly, Appellants respectfully request that the rejections of Claims 166-76, 78-82 and 86-93 be reversed.

VIII. CONCLUSION

Appellants respectfully submit that the Examiner has failed to establish anticipation under 35 U.S.C. §102 with respect to the rejections of Claims 65-76, 78-82 and 86-93. Accordingly, Appellants respectfully submit that the anticipation rejections are erroneous in law and in fact and should therefore be reversed by this Board.

The Director is authorized to charge \$500 for the Appeal Brief and any additional fees which may be required, or to credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 112701-593 on the account statement.

Respectfully submitted,

BELL, BOYD & LLOYD LLC

Robert M. Barrett Reg. No. 30,142 Customer No. 29157

Dated: May 16, 2007

BY

CLAIMS APPENDIX

PENDING CLAIMS ON APPEAL OF U.S. PATENT APPLICATION SERIAL NO. 10/057,660

- 65. Primary composition for oral use comprising a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound.
- 66. Primary composition according to claim 65, wherein the lipophilic bioactive compound is obtained, extracted, enriched or purified from a plant, microorganism, yeast or product of animal origin.
- Primary composition according to claim 66, wherein the plant is tomatoes, soya, green tea, green coffee beans, spices, grapes, cocoa, ginger or cereals.
- 68. Primary composition according to claim 66, wherein the microorganism is any type of bacterium which produces a lipophilic bioactive compound.
- Primary composition according to claim 66, wherein the yeast is a yeast which produces a lipophilic bioactive compound.
- 70. Primary composition according to claim 66, wherein the product of animal origin is chosen from the group consisting of a liver extract and a milk fraction.
- 71. Primary composition according to claim 66, wherein the lipophilic bioactive compound is a carotenoid, polyphenol, lipophilic vitamin, flavonoid, isoflavone, curcuminoid, ceramide, proanthocyanidin, terpenoid, sterol, phytosterol, sterol ester, tocotrienol, squalene, or retinoid, alone or as a mixture.
- Primary composition according to claim 65, wherein the lipophilic bioactive compound is a tomato extract, a soybean extract or a mixture thereof.
- 73. Primary composition according to claim 65, in the form of a powder, gel or liquid and which further comprises at least one of vitamin C or tocopherol.

- 74. Primary composition according to claim 65, which further comprises at least one of an emulsifier, a stabilizer or another additive.
- 75. Primary composition according to claim 65, wherein the lipophilic bioactive compound is present in an amount of about 0.05 to 50% by weight of the composition and the whey protein is present in an amount of about 5 to 90% by weight of the composition.
- 76. Primary composition according to claim 75, wherein the whey protein and lipophilic bioactive compound are present in a weight ratio of about 1:1 to 500:1.
- Oral composition comprising the primary composition according to claim 65 in a foodstuff, in a food supplement or in a pharmaceutical preparation.
- 79. Oral composition according to claim 78, wherein the foodstuff is a yogurt, a liquid drink, a chocolate containing product, an ice cream, cereal, coffee or animal food.
- 80. Oral composition according to claim 78, wherein the food supplement further comprises at least one of a sweetener, a stabilizer, a flavoring or a colorant and is provided in the form of sugar-coated tablets, pills, gelatin capsules, a syrup, a gel or a cream.
- 81. Oral composition according to claim 78, wherein the content of the primary composition is between about 0.001 and 100% by weight of the oral composition.
- 82. Oral composition according to claim 81, wherein the content of the primary composition is between about 10 and 50% by weight of the oral composition.
- 86. The primary composition according to claim 72, wherein the lipophilic bioactive compound is present in an amount of about 0.05 to 50% by weight of the composition and the whey protein is present in an amount of about 5 to 90% by weight of the composition and wherein the whey protein and the lipophilic bioactive compound are present in a weight ratio of about 1:1 to 500:1.
- 87. Oral composition comprising the primary composition according to claim 86, in a foodstuff, in a food supplement or in a pharmaceutical preparation.

- 88. Oral composition according to claim 87, wherein the foodstuff is a yogurt, a liquid drink, a chocolate containing product, an ice cream, cereal, coffee or animal food, or the pharmaceutical preparation is provided in the form of sugar-coated tablets, pills, gelatin capsules, a syrup, a gel or a cream.
- Oral composition according to claim 88, wherein the food supplement further comprises at least one of a sweetener, a stabilizer, a flavoring or a colorant.
- 90. Primary composition for oral use comprising a mixture of (i) at least one lipophilic bioactive compound and (ii) a whey protein in an amount effective to increase the bioavailability of the lipophilic bioactive compound, wherein the lipophilic bioactive compound is present in an amount of about 0.05 to 50% by weight of the composition and the whey protein is present in an amount of about 5 to 90% by weight of the composition and wherein the whey protein and the lipophilic bioactive compound are present in a weight ratio of about 1:1 to 500:1.
- 91. Oral composition comprising the primary composition according to claim 90, in a foodstuff, in a food supplement or in a pharmaceutical preparation.
- 92. Oral composition according to claim 91, wherein the foodstuff is a yogurt, a liquid drink, a chocolate containing product, an ice cream, cereal, coffee or animal food, or the pharmaceutical preparation is provided in the form of sugar-coated tablets, pills, gelatin capsules, a syrup, a gel or a cream.
- 93. Oral composition according to claim 92, wherein the food supplement further comprises at least one of a sweetener, a stabilizer, a flavoring or a colorant.

EVIDENCE APPENDIX

EXHIBIT A: Final Office Action dated August 3, 2006

EXHIBIT B: Advisory Action dated December 11, 2006

EXHIBIT C: U.S. Patent No. 5,643,623 to Schmitz et al. ("Schmitz"), cited by the Examiner in

the Office Action dated August 3, 2006

EXHIBIT D: Affidavit of Karlheinz Bortlik under 37 C.F.R. §1.132

RELATED PROCEEDINGS APPENDIX

None.